

### REMARKS

The examiner has maintained the rejection of independent claim 1 under 35 USC 102(e) as being anticipated by Norrby.

The examiner has misunderstood Norrby. As we explain in detail below, Norrby is, if anything, powerful evidence of the nonobviousness of the invention. We urge the examiner to reconsider and withdraw the rejection.

The invention, as laid out in claim 1, is a “method for selecting the power of an intraocular lens.” The claim calls for “performing autorefracton on the aphakic eye to provide one or more aphakic refraction measurements” and “determining the power of the intraocular lens from the one or more aphakic refraction measurements.” This is a bold departure from the conventional approach of using pre-operative corneal measurements to determine the power of the intraocular lens. Instead of estimating the intraocular power from preoperative measurements, the invention determines the power from refraction measurements made using autorefracton after the natural lens is removed (aphakic eye).

Further limitations have been added to claim 1 to make clear what is meant by “power” and to more clearly define the differences from Norrby and the other prior art of record (but applicant preserves the right to pursue the original claim in a continuation). Some of the new limitations come from dependent claims 5-7, which have been amended accordingly. Minor other amendments have been made to a couple of dependent claims.

The power of a lens is its spherical correction. It is prescribed in units of measure known as diopters. A lens can also have small variations from the spherical to correct for higher order aberrations in the eye, but these have nothing to do with the power of the lens, as they do not change the overall spherical shape. The overall correction of the lens is the combination of the spherical shape prescribed by the power and the higher-order aberrations.

Norrby does take refractive measurements of the aphakic eye, but these are not used to determine the power of the intraocular lens. Instead, they are used for the very different purpose of prescribing higher order aberrations. Norrby is very clear on this. He bases the power of the lens on preoperative measurements, not on refractive measurements of the aphakic eye.

Early on in the description, Norrby makes it clear beyond any possible doubt that the power of the lens (not the higher order aberrations) are to be based on conventional methods (4:16-19; emphasis added):

The second step of the method is to select the power of the intraocular lens, which is done according to conventional methods for the specific need of optical correction of the eye, for example the method described in U.S. Pat. No. 5,968,095

The patent referenced by Norrby is from the 1960s, and clearly teaches that the power is selected based on preoperative measurements, and thus not on measurements of the aphakic eye (Abstract):

A method of preoperatively selecting an intraocular lens to be implanted into an eye to postoperatively render the eye emmetropic or ametropic with a desired postoperative refraction comprises determining the location of the lens haptic plane of the eye, the corneal power of the eye and the axial length of the eye, choosing the desired postoperative refraction and assuming a lens to be implanted, the lens having a known power and geometry, including an offset between the lens haptic plane and an anterior vertex of the lens as if it was in its implanted state. With these parameters and refractive indices of the ocular fluids, a calculation is made to determine whether or not, postoperatively, focus will fall on the retina of the eye. If, from the calculation, it is determined that focus will not fall on the retina of the eye, another lens with a different power and/or geometry is assumed to be implanted and the calculation is repeated until the focus is calculated to fall on the retina of the eye. A lens of the nearest power available for which focusing on the retina was calculated is then selected for implantation.

Norrby repeats this instruction to use preoperative measurements to set the power of the lens in a later paragraph (5:33-37). This is the same paragraph on which the examiner mistakenly relies for his rejection. The examiner writes (page 2) that Norrby:

“determine[es] the power of the intraocular lens from the one or more aphakic refraction measurements (col. 5, lines 33-37; col. 10, lines 17-34; col. 11, lines 29-65).

This conclusion by the examiner is contrary to everything taught in Norrby. For example, the paragraph at col. 5, lines 33-37, in fact, says exactly the opposite of what the examiner concludes. The paragraph refers back to the earlier instruction to use preoperative corneal measurements to set the power (5:33-37):

Preferably, the mentioned corneal measurements also include the measurement of the corneal refractive power. The power of the cornea and the axial eye length are typically considered for the selection of the lens power in the inventive design method.

Corneal measurements are done preoperatively, and are measurements of the shape of the cornea. The invention does not call for corneal measurements, but instead for refractive measurements, which measure how light is refracted by passage through the eye to the retina.

Norrby repeats the instruction to use conventional, preoperative measurements to set the power at still a third location in the patent (8:66-9:3):

The lens is also suitably provided with an optical power. This is done according to conventional methods for the specific need of optical correction of the eye. Preferably the refractive power of the lens is less than or equal to 30 diopters.

Clearly, Norrby is using preoperative corneal measurements – not aphakic refractive measurements – to determine the optical power.

The examiner has relied on three selections from Norrby for his erroneous conclusion to the contrary (at pages 2 and 5 of the office action): (1) col. 5, lines 33-37; (2) col. 10, lines 17-34, and (3) col. 11, lines 29-65. We dealt earlier with why the first (col. 5, lines 33-37) did not support the examiner's conclusion. Neither of the other two are any better for the examiner.

The examiner's second selection reads as follows (col. 10, lines 17-34, emphasis added):

According to another embodiment, the present invention is directed to the selection of an intraocular lens of refractive power, suitable for the desired optical correction that the patient needs, from a plurality of lenses having the same power but different aberrations. The selection method is similarly conducted to what has

been described with the design method and involves the characterizing of at least one corneal surface with a mathematical model by means of which the aberrations of the corneal surface is calculated. The optical system of the selected lens and the corneal model is then evaluated so as to consider if sufficient reduction in aberrations is accomplished by calculating the aberrations of a wavefront arriving from such a system. If an insufficient correction is found a new lens is selected, having the same power, but different aberrations. The mathematical models employed herein are similar to those described above and the same characterization methods of the corneal surfaces can be employed.

The paragraph simply deals with how Norrby selects a set of aberrations to use with the pre-established power. There is nothing to support the examiner's view that the power of the lens is based on aphakic refraction measurements.

The examiner's third selection also provides no support for his conclusion (col. 11, lines 29-65, emphasis added):

In accordance with an especially preferred embodiment, the invention relates to an intraocular lens, which has at least one surface, when expressed as a linear combination of Zernike polynomial terms using the normalized format, that has a negative  $11^{th}$  term of the fourth order with a Zernike coefficient  $a_{11}$  that can balance a positive such term of the cornea to obtain sufficient reduction of the spherical aberration of the eye after implantation. In one aspect of this embodiment, the Zernike coefficient  $a_{11}$  of the lens is determined so as to compensate for an average value resulting from a sufficient number of estimations of the Zernike coefficient  $a_{11}$  in several corneas. In another aspect, the Zernike coefficient  $a_{11}$  is determined to compensate for the individual corneal coefficient of one patient. The lens can accordingly be tailored for an individual with high precision.

The invention further relates to another method of providing a patient with an intraocular lens, which at least partly compensates for the aberrations of the eye. This method comprises removing the natural lens from the eye. Surgically removing the impaired lens can be performed by using a conventional phacoemulsification method. The method further comprises measuring the aberrations of the aphakic eye, not comprising a lens, by using a wavefront sensor. Suitable methods for wavefront measurements are found in J. Opt. Soc. Am., 1994, Vol 11(7), pp. 1949-57 by Liang et. al. Furthermore, the method comprises selecting from a kit of lenses a lens that at least partly compensates for the measured aberrations and implanting said lens into the eye. The kit of lenses comprises lenses of different power and different aberrations and finding the most

suitable lens can be performed in a manner as earlier discussed. Alternatively, an individually designed lens for the patient can be designed based on the wavefront analysis of the aphakic eye for subsequent implantation. This method is advantageous, since no topographical measurements of the cornea are and the whole cornea, including the front and back surfaces, is automatically considered.

These two paragraphs detail how the aberrations of the aphakic eye – not the power -- are measured following surgery. The only reference to how the power is selected is the reference to the “manner earlier discussed”, which clearly is a reference to the use of preoperative measurements to determine the power.

As noted at the outset, Norrby is, if anything, powerful evidence of nonobviousness. This is because although Norrby considers aphakic refraction measurements for estimating aberrations, Norrby fails to appreciate that aphakic refraction measurements could actually be used for determining the intraocular power.

Accordingly, claim 1 as amended is allowable over the art of record.

The remaining claims are all properly dependent on claim 1, and thus allowable therewith. Each of the dependent claims adds one or more further limitations that enhance patentability, but those limitations are not presently relied upon. For that reason, and not because applicants agree with the examiner, no rebuttal is offered to the examiner's reasons for rejecting the dependent claims.

Allowance of the application is requested.

Please apply any other charges or credits to deposit account 06-1050.

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Respectfully submitted,

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